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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,032	06/29/2001	Christoph Seidel	HUBR-1067.3 DIV	2111

24972 7590 12/12/2002
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EXAMINER

WORTMAN, DONNA C

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/12/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,032

Applicant(s)

SEIDEL ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim 27 was amended and two new claims were added in Paper No. 6. In accordance with 37 CFR 1.126, the additional claims have been renumbered as claims 37 and 38. Claims 27-38 are pending and under examination.

The terminal disclaimer filed on September 16, 2002, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,306,579 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 as amended recites "A method for recognition of seroconversion" but recites only two steps "incubating a sample taken from a subject, under reducing conditions ... with at least one polypeptide ... from a hepatitis C virus protein NS3 region which is immunologically reactive ..." and "determining binding ... to recognize seroconversion." It is not understood how "seroconversion" can be recognized in a sample taken from a subject at a single time point; clearly some comparison would be required. Lacking enough steps to define a method for recognition of seroconversion, claim 27 is incomplete and merely defines an immunoassay as presently recited.

Applicant has argued that the term "seroconversion" was known in the art at the time the application was filed and has cited three documents in support.

This argument has been considered but not found persuasive for the following reasons: first, the content of the documents cited could not be evaluated because

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apparently no copies were received, and second, the rejection for indefiniteness was not based on lack of definition of the term "seroconversion" but rather on the lack of sufficient process steps to define a method of determining seroconversion.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 27 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP06074956, with English translation, of record. JP06074956 discloses that immunoassays using antigens from

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the HCV NS3 region are improved by being conducted in the presence of a reducing agent in order to prevent aggregation due to the relatively cysteine-rich nature of the NS3 region. Because claim 27 is incomplete as discussed above, and recites only minimal immunoassay steps, JP06074956 is deemed to anticipate the method as claimed.

Applicant has argued that claim 27 is not incomplete and that the cited art does not anticipate it.

This argument has been considered but not found persuasive because the claim is indefinite as set forth above, since a process is generally considered to be defined by its process steps and the only steps recited in claim 27 are those for an immunoassay as disclosed by JP06074956.

Claim 27 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP06074956 in view of either of Beach et al. (Journal of Medical Virology 36(3):226-227, 1992) or Vallari et al. (Journal of Clinical Microbiology 30(3):552-556, 1992), cited on PTO 892, attached. The teachings of JP06074956 are set forth above. JP06074956 does not explicitly disclose that NS3 antigen in the presence of a reducing agent is to be used to detect "seroconversion." Both Beach et al. and Vallari et al. disclose the use of HCV NS3 antigen to detect antibodies at seroconversion. See, e.g., Beach et al., page 229, Table I, and Vallari et al., page 554, first paragraph. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the assay method disclosed in JP06074956 to detect anti-HCV antibodies early in the course of HCV infection, at seroconversion as taught by either of Beach et al. or Vallari

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et al., when antibody levels are relatively low or when they first appear, because JP06074956 discloses that using an HCV NS3 antigen with the addition of a reducing agent improves the sensitivity of immunoassays for anti-HCV NS3 antibodies and because Beach et al. and Vallari et al. teach that anti-HCV NS3 antibodies appear and are detectable at seroconversion. Because claim 28 is indefinite as discussed above, and it is not clear whether "seroconversion" as recited in the preamble is limiting, the claim is also rejected under 35 USC 103(a).

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP06074956 and either of Beach et al. or Vallari et al. as cited above, and further in view of US Patent Re. 32,696 to Schuurs et al., cited on PTO 892, attached. JP06074956 and either of Beach et al. or Vallari et al. teach immunoassay for HCV seroconversion using HCV NS3 antigen in the presence of reducing conditions as set out above. JP06074956 generally discloses immunoassays in a variety of formats, but JP06074956, Beach et al. or Vallari et al. do not explicitly disclose the immunoassay format for anti-HCV NS3 antibodies in which a first NS3 polypeptide is bound to a solid phase and a second, labeled NS3 polypeptide is in solution. Schuurs et al. disclose the immunoassay format for any antibodies, including hepatitis antibodies, in which an antigen is surface-bound and a second antigen with the same immunochemical properties as the first is labeled and in solution. It would have been obvious to perform an immunoassay for recognition of seroconversion as taught by JP06074956 and either of Beach et al. or Vallari et al. using the assay format of Schuurs et al. because Schuurs et al. discloses that format as being generally applicable and sensitive.

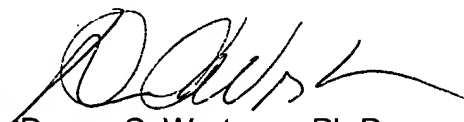
Applicant has argued that the previously cited art does not teach or suggest detection of seroconversion, but rather that when reducing conditions were used, the assays were more sensitive.

This argument has been considered but not found persuasive as regards the rejection as now made; either of Beach et al. or Vallari et al. teach seroconversion and are cited for that teaching.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
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